



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0465; FRL-9983-79]

S-Metolachlor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of S-metolachlor in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0465, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to

4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0465 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0465, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of January 26, 2018 (83 FR 3658) (FRL-9971-46), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E8587) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of NJ, 500 College Road East, Suite 201 W,

Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide S-metolachlor including its metabolites and degradates in or on the raw agricultural commodities stevia, dried leaves at 15.0 parts per million (ppm); vegetable, leaves of root and tuber, group 2, except sugar beet at 2.0 ppm; Swiss chard at 0.10 ppm; vegetable, *Brassica*, head and stem, group 5–16 at 0.60 ppm; *Brassica*, leafy greens, subgroup 4–16B, except Chinese broccoli at 1.8 ppm; stalk and stem vegetable subgroup 22A, except celtuce, Florence fennel, and kohlrabi at 0.10 ppm; leaf petiole vegetable subgroup 22B at 0.10 ppm; cottonseed subgroup 20C at 0.10 ppm; celtuce at 0.10 ppm; Florence fennel at 0.10 ppm; kohlrabi at 0.60 ppm, and Chinese broccoli at 0.60 ppm. In addition, the petition requested to amend 40 CFR 180.368 by removing the tolerances for S-metolachlor in or on asparagus at 0.10 ppm; beet, garden, leaves at 1.8 ppm; turnip, greens at 1.8 ppm; *Brassica*,

head and stem, subgroup 5A at 0.60 ppm; *Brassica*, leafy greens, subgroup 5B at 1.8 ppm; cotton, undelinted seed at 0.10 ppm; and leaf petioles, subgroup 4B at 0.10 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being established as well as some of the commodity definitions. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for S-metolachlor including exposure resulting from the

tolerances established by this action. EPA's assessment of exposures and risks associated with S-metolachlor follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Since the last time S-metolachlor was reviewed, the toxicology database was re-evaluated to incorporate new toxicity data and to update endpoints selected for points of departure to be consistent with current Agency policies and practices. An inhalation toxicity study for metolachlor was received and incorporated into the risk assessment and consequently, the 10x database uncertainty factor from previous assessments was removed for the inhalation scenarios since this is no longer a data gap. Also, new endpoints were selected and updated dietary and occupational/residential exposure assessments were completed based on the updated toxicological endpoints and reflect recent updates to EPA's standard operating procedures (SOPs) and policies.

The existing toxicological database is primarily comprised of studies conducted with metolachlor. The toxicology database for S-metolachlor consists of bridging data. Bridging studies indicate that the metolachlor toxicology database can be used to assess toxicity for S-metolachlor, and *vice versa*. In subchronic (metolachlor and S-metolachlor) and chronic (metolachlor) toxicity studies in dogs and rats decreased body weight was the most commonly observed effects. Chronic exposure to metolachlor in rats also resulted in increased liver weight and microscopic liver lesions (foci of cellular alteration) in both sexes. No systemic toxicity was

observed in rabbits when metolachlor was administered dermally. There was no evidence of systemic toxicity at the limit dose in a 28-day inhalation study in rats with metolachlor, although portal of entry effects occurred in the nasal cavity at lower doses. These effects included hyperplasia of the squamous epithelium and subacute inflammation and mucous cell hyperplasia. There is no evidence of immunotoxicity in the submitted mouse immunotoxicity study.

Prenatal developmental studies in the rat and rabbit with both metolachlor and S-metolachlor revealed no evidence of a qualitative or quantitative susceptibility in fetal animals. A 2-generation reproduction study with metolachlor in rats showed evidence of quantitative susceptibility. Decreased pup body weight in the F1 and F2 litters was seen in the absence of maternal toxicity. There are no acute or subchronic neurotoxicity studies available for S-metolachlor or metolachlor. In the developmental rat study, clinical signs of neurotoxicity were observed in pregnant dams but only at the limit dose of 1,000 mg/kg/day. There was no other evidence of clinical signs of neurotoxicity in adult animals in the database. There are no residual uncertainties with regard to pre- and/or postnatal toxicity.

Metolachlor has been evaluated for carcinogenic effects in the mouse and the rat. Although treatment with metolachlor did not result in an increase in treatment-related tumors in male rats or in male or female mice, metolachlor caused an increase in liver tumors in female rats. There was no evidence of mutagenic or cytogenetic effects *in vivo* or *in vitro*. Based on the information available in 1994, metolachlor was classified as a Group C possible human carcinogen, in accordance with the 1986 Guidelines for Carcinogen Risk Assessment. Based on that classification and consistent with the data available at that time, EPA determined that a

non-linear approach (i.e., reference dose (RfD)) would be protective for all chronic toxicity, including carcinogenicity, that could result from exposure to metolachlor.

In 2017, EPA re-assessed the cancer classification for metolachlor in order to take into account additional mechanistic studies on S-metolachlor that were submitted to assess a human relevance framework analysis for a mitogenic mode of action (MOA) for liver tumors in female rats. Based on comparable effects of S-metolachlor and metolachlor shown in several associative events supporting the mode of action hypothesis, the Agency concluded that the *in vitro* and *in vivo* data reasonably explains the tumorigenic effects of metolachlor and adequately demonstrates dose and temporal concordance to support key events for the MOA leading to liver tumors in female rats. Specifically, the Agency found that the development of liver tumors in rats orally administered metolachlor is initiated by activation of constitutive androstane receptor (CAR) in liver hepatocytes followed by altered gene expression, transient increased cell proliferation, increased hepatocellular foci, and hepatocyte toxicity (increased liver weight and liver hypertrophy). Consequently, in accordance with the EPA's Final Guidelines for Carcinogen Risk Assessment (March 2005), EPA has reclassified metolachlor/S-metolachlor as "Not Likely to be Carcinogenic to Humans" at doses that do not induce cellular proliferation in the liver. This classification was based on convincing evidence of a CAR-mediated mitogenic MOA for liver tumors in female rats. Because the current chronic RfD is protective for any proliferative responses in the liver and the other key events in the MOA for the formation of liver tumors, a non-linear approach (i.e., RfD) adequately accounts for all the chronic toxicity, including carcinogenicity, that could result from exposure to metolachlor/S-metolachlor.

Specific information on the studies received and the nature of the adverse effects caused by S-metolachlor as well as the no-observed-adverse-effect-level (NOAEL) and the

lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document titled "S-metolachlor: Human Health Risk Assessment for (1) Establishment of Tolerances for New Uses on Chicory, Stevia and Swiss Chard; (2) Tolerance Translations from Table Beet Tops, Turnip Greens, and Radish Tops to Crop Group 2 (Leaves of Root and Tuber Vegetables), except Sugar Beets; (3) Tolerance Conversions (i) from Crop Subgroup 4B to Crop Subgroup 22B (Leaf Petiole Vegetable), (ii) from Crop Subgroup 5A to Crop Group 5-16 (*Brassica*, Head and Stem Vegetable) and (iii) from Crop Subgroup 5B to Crop Subgroup 4-16B (*Brassica* Leafy Greens); and (4) Tolerance Expansions of Representative Commodities to (i) Cottonseed Subgroup 20C, and (ii) Stalk and Stem Vegetable Subgroup 22A, except Kohlrabi" on pages 54-64 in docket ID number EPA-HQ-OPP-2017-0465.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general

principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for S-metolachlor used for human risk assessment is shown in Table 1 of this unit.

Table 1. Summary of Toxicological Doses and Endpoints for S-metolachlor for use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	An acute dietary assessment for all populations is not required. The adverse effects resulting from a single dose in the developmental rat study with metolachlor occurred at the limit dose of 1,000 mg/kg/day, which is a dose that is not relevant for risk assessment. In addition, an endpoint was not selected for Females 13-49 years old since no developmental effects attributable to a single exposure were identified in the metolachlor/S-metolachlor database.		
Chronic dietary (All populations)	NOAEL= 26 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.26 mg/kg/day cPAD = 0.26 mg/kg/day	2-generation reproduction study in rats (Metolachlor) LOAEL = 86 mg/kg/day based on decreased pup body weight in F1 and F2 litters
Incidental oral short-term (1 to 30 days)	NOAEL= 26 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	2-generation reproduction study in rats (Metolachlor) LOAEL = 86 mg/kg/day based on decreased pup body weight in F1 and F2 litters
Dermal short- and intermediate-term (1-6 months)	NOAEL= 26 mg/kg/day Dermal absorption factor	LOC for MOE = 100	2-generation reproduction study in rats (Metolachlor)

<i>(Children only)</i>	(DAF) = 58% UF _A = 10x UF _H = 10x FQPA SF = 1x		LOAEL = 86 mg/kg/day based on decreased pup body weight in F1 and F2 litters
Cancer (Oral, dermal, inhalation)	Classification: Metolachlor/S-metolachlor has been classified as “Not Likely to be Carcinogenic to Humans” at doses that do not induce cellular proliferation in the liver, with risk quantitated using a non-linear (RfD) approach.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to S-metolachlor, EPA considered exposure under the petitioned-for tolerances as well as all existing S-metolachlor tolerances in 40 CFR 180.368. EPA assessed dietary exposures from S-metolachlor in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for S-metolachlor; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 2003-2008 food consumption data from the United States Department of Agriculture’s (USDA)

National Health and Nutrition Examination Survey/What We Eat in America, (NHANES/WWEIA).

As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT).

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to S-metolachlor. Therefore, a separate quantitative cancer exposure assessment is unnecessary since the chronic dietary risk estimate will be protective of potential cancer risk.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue or PCT information in the dietary assessment for S-metolachlor. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for S-metolachlor in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of S-metolachlor. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

The Agency assessed parent metolachlor, and the metabolites CGA-51202 (metolachlor-OA), CGA-40172, and CGA-50720 together in the drinking water assessment using a total toxic residues (TTR) approach where half-lives were recalculated to collectively account for the parent and the combined residues of concern.

Based on the Surface Water Concentration Calculator (SWCC), the Pesticide Root Zone Model Ground Water (PRZM GW), and the Screening Concentration in Ground Water (SCI-GROW), the estimated drinking water concentrations (EDWCs) of S-metolachlor and its metabolites for chronic exposures are estimated to be 43.70 ppb for surface water and 978 ppb in ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration of value 978 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

S-metolachlor is currently registered for the following uses that could result in residential exposures: on commercial (sod farm) and residential warm-season turf grasses and other non-crop land including golf courses, sports fields, and ornamental gardens. EPA assessed residential exposure using the following assumptions: For residential handlers, in previous human health risk assessments for S-metolachlor, inhalation exposure and risk to residential handlers was assessed and resulted in no risks of concern. Based on current Agency policy, the Agency no longer considers these products to be intended for homeowner use due to label requirements for specific clothing and personal protective equipment; therefore, a quantitative residential handler assessment was not conducted.

There is the potential for post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with S-metolachlor. The population

groups at risk are youth 11 to <16 years old, children 6 to <11 years old, and children 1 to <2 years old. The worst-case scenarios used in the aggregate risk assessment are as follows:

- For youth 11 to <16 years old, the scenario used is dermal exposures from post-application exposure to treated turf during golfing activities.
- For children 6 to <11 years old, the scenario used is dermal exposures from post-application contact with treated gardens.
- For children 1 to <2 years old, the scenario used is hand-to-mouth exposures from post-application exposure to treated turf.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found S-metolachlor to share a common mechanism of toxicity with any other substances, and S-metolachlor does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that S-metolachlor does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at

<http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Acceptable developmental toxicity studies in the rat and rabbit with both metolachlor and S-metolachlor and an acceptable reproduction study in the rat with metolachlor are available with clearly defined LOAELs and NOAELs. No developmental toxicity was seen in rats or rabbits with either compound. In the metolachlor and S-metolachlor rat prenatal developmental toxicity studies there were no developmental effects seen up to the limit dose. In the rat developmental toxicity study with metolachlor, death and clinical signs (clonic and/or tonic convulsions, excessive salivation, urine-stained abdominal fur) were observed at the limit dose in maternal animals in the absence of developmental toxicity. In the S-metolachlor rabbit developmental toxicity study, clinical signs of toxicity (little/none/soft stool) were observed in maternal animals in the absence of developmental effects. In the two-generation reproduction study in rats conducted with metolachlor, there was quantitative evidence of susceptibility. Decreased pup body weight in F1

and F2 litters was seen in the absence of maternal toxicity. The 2-generation reproduction study was used for endpoint selection, therefore, the PODs selected are protective of the effects seen at this dose.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

- i. The toxicity database for S-metolachlor is complete.
- ii. There is no indication that S-metolachlor is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that S-metolachlor results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies. In the 2-generation reproduction study in rats conducted with metolachlor, there was quantitative evidence of susceptibility, however, the 2-generation reproduction study was used for endpoint selection, therefore, the PODs selected are protective of the effects seen at this dose.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to S-metolachlor in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by S-metolachlor.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, S-metolachlor is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure analysis, EPA has concluded that the risk estimates for chronic exposure to S-metolachlor from food and water are not of concern (<100% of cPAD) with a risk estimate at 22% of the cPAD for all infants less than 1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of S-metolachlor is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

S-metolachlor is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to S-metolachlor.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,246 for youths 11 to less than 16 years old, 106 for children 6 to less than 11 years old, and 207 for children 1 to less than 2 years old, the population groups of concern. Because EPA's level of concern for S-metolachlor is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, S-metolachlor is not registered for any use patterns that would result in intermediate-term residential exposure.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A, the chronic dietary risk assessment is protective of any potential cancer effects. Based on the results of that assessment, EPA concludes that S-metolachlor is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to S-metolachlor residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate methodology is available for enforcing the established and recommended tolerances. PAM Vol. II, Pesticide Regulation Section 180.368, lists a gas chromatography with nitrogen-phosphorus detector (GC/NPD) method (Method I) for determining residues in/on

plant commodities and a gas chromatography with mass selective detector (GC/MSD) method (Method II) for determining residues in livestock commodities. These methods determine residues of metolachlor and its metabolites as either CGA-37913 or CGA-49751 following acid hydrolysis (LOQs of 0.03 ppm and 0.05 ppm, respectively).

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established any MRLs for either S-metolachlor or metolachlor.

C. Response to Comments

Four comments were submitted to the docket for this action. One dealt with “logging workers in the National Forest”, the second with critical habitat restrictions, the third with wind powered facilities threatening populations of bats, and the fourth with adverse economic impacts of regulations. All submitted comments are unrelated to S-metolachlor in particular, or pesticides in general, and are not relevant to this action.

D. Revisions to Petitioned-For Tolerances

The submitted Swiss chard field trial data support a tolerance of 0.15 ppm instead of the proposed tolerance of 0.10 ppm. The reason for the difference is that EPA used the combined level of quantitation (LOQ) of CGA-37913 and CGA-49751 expressed in parent equivalents, 0.131 ppm, which becomes 0.15 ppm in Organization for Economic Cooperation and Development (OECD) rounding class representing the tolerance value for Swiss chard. The petitioner, instead, used the combined LOQ of 0.10 ppm for the input dataset of the OECD tolerance calculation procedure.

Chinese broccoli was a member of subgroup 5A with a tolerance of 0.60 ppm, which falls within the established tolerance for subgroup 4-16B at 1.8 ppm. An individual tolerance for Chinese broccoli is not needed.

Celtuce and Florence fennel, originally in crop subgroup 4B, have the same tolerance as subgroup 22A, 0.10 ppm. Following crop group conversion/revision the tolerances for celtuce and Florence fennel are now covered by the subgroup 22A.

EPA also modified several commodity definitions to be consistent with Agency nomenclature.

V. Conclusion

Therefore, tolerances are established for residues of S-metolachlor in or on *Brassica*, leafy greens, subgroup 4-16B at 1.8 ppm; Cottonseed subgroup 20C at 0.10 ppm; Kohlrabi at 0.60; Leaf petiole vegetable subgroup 22B at 0.10 ppm; Stalk and stem vegetable subgroup 22A, except kohlrabi at 0.10 ppm; Stevia, dried leaves at 15 ppm; Swiss chard at 0.15

ppm; Vegetable, *Brassica*, head and stem, group 5-16 at 0.60 ppm; and Vegetable, leaves of root and tuber, group 2, except sugar beet at 2.0 ppm.

Additionally, due to the establishment of the aforementioned commodities, the following tolerances are removed as unnecessary: Asparagus; Beet, garden, leaves; *Brassica*, head and stem, subgroup 5A; *Brassica*, leafy greens, subgroup 5B; Cotton, undelinted seed; Leaf petioles, subgroup 4B; and Turnip greens.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCa section 408(d), such as the tolerances in this final rule, do not require the issuance of a

proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 *note*).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 26, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.368(a)(2):

- a. Remove the entries for “Asparagus”; “Beet, garden, leaves”; “Brassica, head and stem, subgroup 5A”; and “Brassica, leafy greens, subgroup 5B” from the table.
- b. Add alphabetically the entry for “*Brassica*, leafy greens, subgroup 4-16B” to the table.
- c. Remove the entry for “Cotton, undelinted seed” from the table.
- d. Add alphabetically the entries for “Cottonseed subgroup 20C” and “Kohlrabi” to the table.
- e. Remove the entry for “Leaf petioles, subgroup 4B” from the table.
- f. Add alphabetically the entries for “Leaf petiole vegetable subgroup 22B”; “Stalk and stem vegetable subgroup 22A, except kohlrabi”; “Stevia, dried leaves”; and “Swiss chard” to the table.
- g. Remove the entry for “Turnip greens” from the table.
- h. Add alphabetically the entries for “Vegetable, *Brassica*, head and stem, group 5-16” and “Vegetable, leaves of root and tuber, group 2, except sugar beet” to the table.

The additions read as follows:

§ 180.368 Metolachlor; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
* * * * *	
<i>Brassica</i> , leafy greens, subgroup 4-16B	1.8
* * * * *	
Cottonseed subgroup 20C	0.10
* * * * *	
Kohlrabi	0.60
Leaf petiole vegetable subgroup 22B	0.10
* * * * *	
Stalk and stem vegetable subgroup 22A, except kohlrabi	0.10
Stevia, dried leaves	15
* * * * *	
Swiss chard	0.15
* * * * *	
Vegetable, <i>Brassica</i> , head and stem, group 5-16	0.60
* * * * *	
Vegetable, leaves of root and tuber, group 2, except sugar beet	2.0
* * * * *	

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